PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Thomas R. Adams *et al.*

Serial No.: 08/113,561

Filed: August 25, 1993

For: METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND CELLS THEREOF

Group Art Unit: 1638

Examiner: Fox, David T.

Atty. Dkt. No.: DEKM:055US

CERTIFICATE OF ELECTRONIC SUBMISSION

Date of Submission: November 13, 2006

REPLY BRIEF

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REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit this Reply Brief in response to the Examiner's Answer dated September 13, 2006. The date for filing this Reply Brief is November 13, 2006. No fees are believed due in connection with this paper; however, should any fees be due the Commissioner is authorized to withdraw the appropriate fees from Fulbright & Jaworski Deposit Account No. 50-1212/DEKM:055US.

Please date stamp and return the attached postcard as evidence of receipt.

I. REAL PARTY IN INTEREST

The real party in interest is Monsanto Company, the parent company of wholly owned subsidiary DeKalb Genetics Corp.

II. RELATED APPEALS AND INTERFERENCES

Appeals have been filed in Serial Nos. 09/081,416, 09/732,439 and 10/171,498. These cases are related to the current case, but concern transgenic plants transformed with different transgenes conferring different phenotypes and thus are not believed to be relevant to this appeal, but are identified here in the event they should be of interest to the Board. Ser. No. 09/081,416 is a divisional application of this case; Ser. No. 09/732,439 is a divisional of a CIP of this case; and Ser. No. 10/171,498 is a continuation of a continuation application that was a CIP of this application. Decisions issued in Ser. No. 09/081,416 and Ser. No. 09/732,439, copies of which are included in the related proceedings appendix.

III. STATUS OF THE CLAIMS

Claims 1-68 were filed. Claims 1, 5-66 and 68 were canceled. Claims 2-4 and 67 are therefore currently pending and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to fertile, transgenic maize plants transformed with a DNA sequence encoding a fatty acid desaturase gene, wherein the DNA sequence is capable of being

transmitted to subsequent plant progeny and is expressed. Specification at page 306. Expression of the fatty acid desaturase yields one or more phenotypic characteristic that renders the plant identifiable over the corresponding untransformed maize plant which does not comprise the fatty acid desaturase. Specification at page 45, lines 18-19.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(A) Are claims 2-4 and 67 properly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement?

(B) Are claims 2-4 and 67 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification?

Appellants note that the Final Office Action rejected claims 2 and 3 as indefinite under 35 U.S.C. §112, second paragraph, for depending upon a canceled claim. Appellants intend to correct the error by amendment upon the allowance of the case or reopening of prosecution and thus are not appealing the rejection.

VII. REPLY

A. The Claims Meet the Written Description Requirement

1. The Recent Federal Circuit Holding in *Capon v. Eshhar* Requires Reversal of the Rejection

The Examiner fails to apply the proper legal standard in this case, which is set forth in a case decided subsequent to the final Office Action, namely *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). In *Capon*, the issue presented was whether claims directed to chimeric genes having various nucleic acid components must be supported by a specific disclosure of the nucleic acid sequences that make up the chimeric genes when the underlying sequences were known in

the art. *Id.* at 1355. The Board of Patent Appeals and Interferences had held that such a disclosure was required and found the claims invalid for lack of an adequate written description. The Board summarized its holding as follows:

> Here, both [parties to the interference] claim novel genetic material described in terms of the functional characteristics of the protein it encodes. Their specifications do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.

Id.

Both parties appealed and the Federal Circuit reversed, explaining that the "genes here at issue are prepared from known DNA sequences of known function" and that the written description requirement does not "require a re-description of what was already known." *Id.* at 1358. The Court discussed the cases relied upon by the Board for its decision, explaining that in *Lilly* "the cDNA for human insulin had never been characterized"; in *Fiers* "much of the DNA sought to be claimed was of unknown structure" and in *Amgen* "a novel gene was not adequately characterized by its biological function alone because such a description would represent a mere 'wish to know the identity' of the novel material." *See Id.*, *citing Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993) and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991). Finally, the Court explained that *University of Rochester* merely found that the description of the COX-2 enzyme itself did not serve to describe unknown compounds capable of selectively inhibiting the enzyme. *Capon*, 418 F.3d at 1358, citing *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (Fed. Cir. 2004). Based on this, the Federal Circuit held that:

> The 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. Both [parties to the interference] explain that this ***invention does not concern the discovery of gene function or structure***, as in *Lilly*. The chimeric genes here at issue are prepared from known DNA sequences of known function. The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the ***claimed chimeric genes***.

Capon, 418 F.3d at 1358 (emphasis added). The Federal Circuit therefore emphasized that cases involving the use of known nucleic acids must be analyzed differently for purposes of the written description requirement than those that claim novel nucleic acids.

In the current appeal, the same issue is presented and the Examiner attempts to take the same position rejected by the Federal Circuit in *Capon*. The Examiner also relies upon many of the same cases discussed by the court in *Capon*. As noted by the *Capon* panel, *Lilly*, *Amgen* and *University of Rochester* turned on the description of a ***novel substance*** and are distinguishable from the situation in which a known composition is merely a component of the claimed invention. As in *Capon*, the current claims do not involve the discovery of new genes but rather relate to plants transformed with ***known genes***. These genes were well known in the art as established in Appellants' Appeal Brief (*see*, *e.g.*, Exhibits A-G, discussed more fully below).

The *Capon* panel found this claim scope distinction to be dispositive and emphasized that the level of skill in the art must be taken into account for a written description analysis, stating that "[t]he written description requirement must be applied in the context of the particular invention and the state of the knowledge." *Id.* The court therefore reversed the Board rejection for lack of written description, and concluded:

> The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.

Id.

2. The Examiner's Answer Misstates the Relevant Law

The Examiner's Answer misinterprets the cited authorities in an attempt to support the rejection. A review of the facts and holdings of these cases reveals that, if anything, they directly support the written description of the claims, as explained below.

(a) The Written Description Guidelines

The Examiner first asserts that the Written Description Guidelines support the rejection because "claims drawn to products containing inadequately described components are themselves inadequately described." Answer at p. 8, 1st full ¶.

However, the Examiner ignores that the Written Description Guidelines require that written description be reviewed "from the standpoint of one of skill in the art at the time the application was filed" and "should include a determination of the field of the invention and the level of skill and knowledge in the art. MPEP §2163(II)(A)(2). *Citing Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)). With respect to the level of skill in the art in the case at issue, the Examiner merely makes the conclusory statement that "the Examiner disagrees that fatty acid desaturase genes were well-known and publicly available prior to Appellant's invention[.]" Answer at p. 8, last ¶. The Examiner provides absolutely no explanation as to how Exhibits A-G of Appellants' Appeal Brief are deficient in demonstrating that fatty acid desaturase genes were well-known and publicly available prior to Appellant's invention. In a previous communication, the Examiner states "All of the references submitted by Applicant were published after April 1990, the effective filing date for the concept of corn

transformation. In addition, many of the submitted references were published after August 1993, the effective filing date for corn transformation with fatty acid desaturase genes." January 26, 2005 Final Office Action, p. 4.

Appellants note that the claims at issue on appeal have an effective filing date of August, 1993. Therefore, the level of skill in the art is measured as of that date, and the April 1990 date is irrelevant for purposes of this analysis. Furthermore, six of the seven exhibits cited in Appellants' Appeal Brief were publicly available before the August 1993 effective filing date. The seventh exhibit (Exhibit F) was published on September 28, 1994, but was filed on March 12, 1992 – before the effective filing date of the instant application. Clearly, these references are indicative of the skill level in the art as of the August 25, 1993 filing date. As shown in Appellants' Appeal Brief, these references also provide specific examples of genes encoding fatty acid desaturases and therefore demonstrate that such genes well known in the art before the August 25, 1993 filing date. Appellants' Appeal Brief, pp. 7-9. It is therefore improper for the Examiner to summarily dismiss such evidence by merely stating that the Examiner "disagrees" that fatty acid desaturases were well-known. Furthermore, the specification itself further describes in detail how such fatty acid desaturase genes alter grain composition traits. *See* Appellants' Appeal Brief, pp. 8-9.

Under §112 it is specifically the burden of the Examiner to determine the level of skill in the art. As stated in the Manual of Patent Examining Procedure (MPEP):

> The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is ***conducted from the standpoint of one of skill in the art*** ***at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art***.

MPEP §2163 (citations omitted) (emphasis added). This is consistent with *Capon*, which notes that "[t]he written description requirement must be applied in the context of the particular invention and the state of the knowledge." *Id.*

Under §112 it is of course also the burden of the Examiner to establish a lack of patentability, rather than the burden of Applicants to prove compliance with the statute. Therefore, the Examiner in this case was ***obligated*** to take into account the level of skill and knowledge in the art. The example references contained in Exhibits A-E and G of Appellants' Appeal Brief were published prior to the effective filing date. The references demonstrate the contemporaneous knowledge of those of skill in the art by disclosing that genes encoding fatty acid desaturases were well known in the art before the August 25, 1993 filing date. Specifically, Exhibits A-G of Appellants' Appeal Brief demonstrate ***at least nine fatty acid desaturases that were known in the art*** as of the effective filing date. This evidence is more than adequate to demonstrate possession of fatty acid desaturases in the context of the ***claimed invention***.

(b) Amgen v. Chugai

The Answer asserts that the holding of *Amgen v. Chugai* supports the rejection because "the claims were not limited to isolated genes. Instead, the claims included *compositions* comprising the proteins encoded by those genes." (Emphasis in original); Answer, p. 9, first full ¶. The Examiner therefore apparently asserts that the situation in *Amgen* was analogous to the current case because the compositions as found in claims 3 and 6 of US 4,677,195 that were the subject of the suit were invalid due to lack of conception of the particular nucleic acid sequence. This is simply incorrect because the subject claims were not directed to a novel composition made up from a ***known*** ingredient, but rather were directed to pharmaceutical compositions that had as their very point of novelty the "homogeneous erythropoietin of claim 1" in the case of claim 3 and "the homogeneous erythropoietin of claim 4" in the case of claim 6. Accordingly,

Amgen's holding of inadequate conception was made for claims directed to "the ***novel***...sequence which codes for EPO." *Amgen v. Chugai*, 927 F.2d 1200, 1216-18 (Fed. Cir. 1991) (emphasis added). Thus, *Amgen* cannot be read to support the rejection, as underscored by the *Capon* decision described above.

(c) Eli Lilly

The Answer also attempts to bootstrap the holding of *Lilly* to the current case in a manner similar to that done for *Amgen* by asserting that claims to "compositions" were at issue. Answer at p. 9, 3rd ¶. However, the *Lilly* claims were invalidated for lack of written description because the very thing that was the ***point of novelty*** was not described in the art or specification. *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997). The holding of *Lilly* in fact makes this very distinction and directly contradicts the Examiner by stating that "naming a type of material generally known to exist, ***in the absence of knowledge as to what that material consists of***, is not a description of that material." *Id.* at 1568 (emphasis added). In fact, *Capon* emphasizes this very point, noting that "[i]n Lilly, the cDNA for human insulin had never been characterized." *Capon*, 418 F.3d at 1357 (citation omitted).

(d) University of Rochester

The Answer also mistakenly asserts that *University of Rochester* supports the written description rejection by contending that the description in that case of the relevant compound (COX-2 inhibitors) by function or assay alone is analogous to the current claims. Answer at p. 10-11, bridging ¶. For example, it is asserted that the phenotypic traits of the claimed plants "are analogous to the 'desired result of its use' prohibited by the Court" in the *Rochester* case. *Id.* However, a reading of this case reveals that the situation at issue in *Rochester* is non-analogous to the current situation and that the Federal Circuit recognizes this difference. The Federal Circuit in particular noted that the patent at issue was invalid for lack of written description

because an inhibitor of COX-2 was not disclosed in the application and there was ***no pre-existing awareness in the art*** of such a compound exhibiting this activity. *See University of Rochester v. G.D. Searle & Co.,* 358 F.3d 916, 927, 69 U.S.P.Q.2d 1886 (Fed. Cir., Feb. 13, 2004). For example, the Federal Circuit stated that "the novelty of those claims, if any, would appear to reside in the fact that COX-2-selective inhibitors were previously unknown." *Id.* at 928 n.7. In the current case there ***is*** such a pre-existing awareness in the art, as demonstrated in Exhibits A-G of Appellants' Appeal Brief. If anything, the *Rochester* case therefore directly supports the written description of the claims.

(e) Bayer

The Answer asserts that *Bayer* is relevant because the Court "did not recognize that Housey had possession of the drug products claimed by Bayer" and as "possession is also a written description issue, *Bayer* is eminently applicable to the instant situation." Answer at p. 11, 1st full ¶. Applicants respectfully submit that this statement misinterprets the issue under consideration in *Bayer*. The issue was patent infringement under 35 U.S.C. §271(g), not written description. *Bayer v. Housey*, 340 F.3d 1367, 1371, 68 U.S.P.Q.2d 1001 (Fed. Cir. 2003). Any "possession" that may have been referred to was in the context of infringement and importation of information gained from patented drug screening assays, not §112. *Id.* at 1371. The case therefore has no relevance to the current written description rejection.

3. Conclusion

As clearly demonstrated by the statutes and case law cited above, there is no requirement that a patent specification re-describe subject matter that is already known in the art. The written description analysis must be performed in view of the level of skill in the art, as well as the scope of the claimed subject matter. In the case at issue, Appellants have submitted as Exhibits A-G evidence showing at least nine fatty acid desaturases known in the art as of the effective filing

date. Coupled with the demonstration in the specification of expression of at least 11 different and diverse transgenes in maize cells and recovery of at least 267 different transgenic lines, Appellants have far more than met the standard under §112. See specification Tables 8 and 9.

In conclusion, Appellants have affirmatively established on the record a written description for the claimed subject matter and demonstrated the lack of any legal or factual basis for doubting the sufficiency of the description. Reversal of the rejection is thus respectfully requested.

B. The Claims Are Enabled

The Answer attempts to counter the showing of enablement made in Appellants' Brief by asserting that (1) Stephanopoulos *et al.* (1993) and Post-Beittenmiller *et al.* (1989) indicate that plant transformation for modifying fatty acid metabolism has generally not been successful and few organisms have had their metabolic pathways altered, (2) given unpredictability allegedly inherent in modifying fatty acid biosynthesis "it is highly unlikely that plant transformation with fatty acid desaturase genes would cause a multitude of phenotypes unrelated to fatty acid content", (3) the holding of *Genentech* supports the rejection, (4) the Ursin Declaration is not persuasive because of use of a "non-exemplified" method of maize transformation and simultaneous expression of two desaturases "one of which was mutated," and (5) Appellants allegedly confirmed the veracity of the Examiner's argument by noting "past failures of others" in the Response of October 18, 2004. As set forth below in the order these issues are raised, none of these arguments supports the rejection.

1. Stephanopoulos et al. (1993) and Post-Beittenmiller et al. (1989) Do Not Support the Rejection

The only alleged evidence for doubting the enablement of the claims provided by the Examiner is a citation to the Stephanopoulos *et al.* (*Tibtech*, 11:392-396, 1993) and Post-

Beittenmiller *et al.* (*The Plant Cell*, 1:889-899, 1989) publications. For example, the Answer asserts that Post-Beittenmiller *et al.* (1989) teach that transformation with an acyl carrier protein (ACP) failed to produce changes in fatty acid synthesis or accumulation and that Stephanopoulos *et al.* shows that "modification of fatty acid accumulation generally has not been successful" and thus the claims are not enabled. Answer at p. 15, 1st and 2nd full ¶. A review of Post-Beittenmiller reveals, however, that the authors in fact "demonstrated that the levels of [transgenic spinach ACP] in tobacco chloroplasts could be ***raised twofold to threefold above the endogenous tobacco ACP***" and this ***increased total ACP levels 3-4 fold***. See p. 895, 2nd col., 2nd full ¶ (emphasis added). The authors also noted that "approximately 5 to 20% of the spinach ACP-I expressed in tobacco leaves was in the C8-C18 acyl form (similar to levels detected in spinach), providing a ***clear demonstration that spinach ACP-I participated*** in tobacco fatty acid metabolism." *Id.* (emphasis added). While it was indicated that an unknown process could have caused the finding, the finding showed a ***detectable phenotypic change***. Consistent with this the current claims require expression of a fatty acid desaturase gene in a transgenic maize plant "so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene..." Enablement must specifically be viewed based on this subject matter, and therefore the reference does nothing to contradict enablement.

With respect to Stephanopoulos, this was a general review that did not focus on any particular species or transgene. The sections relied upon by the Examiner say no more than that some "metabolic engineering" efforts have met with success, while the authors are also aware of other efforts that yielded "marginal results." Again, however, even when the statement is taken as true for purposes of argument, such subjectively "marginal" results are irrelevant to the

objective standard of enablement, particularly when viewed with the other examples that "met with success." The relevant standard is undue experimentation and even marginal success would satisfy this burden. The conclusions of the Examiner regarding these references are thus unfounded, particularly when taken with the evidence in the specification showing expression and recovery of a detectable phenotype using numerous diverse transgenes. In sum, neither reference provides any basis for doubting the substantial evidence of enablement provided by Appellants. As explained below, the rejection must therefore be reversed.

2. Specific Phenotypes "Unrelated To Fatty Acid Type Or Content" Are Irrelevant

The Examiner further asserts that the claims are non-enabled because "it is highly unlikely that plant transformation with fatty acid desaturase genes would cause a multitude of phenotypes unrelated to fatty acid type or content, such as changes in flower color, plant height, etc. as encompassed by the claims." Answer at p. 15, 3rd full ¶. The meaning and relevance of this statement are not understood by Appellants. The claims do not require a "multitude of phenotypes unrelated to fatty acid type or content." Rather the claims require only a phenotypic change that renders the claimed transgenic maize plant identifiable over the corresponding untransformed maize plant. See claim 67. The occurrence of a "multitude of phenotypes unrelated to fatty acid type or content" is therefore completely irrelevant. What is legally relevant is that the specification enables the claimed invention. The evidence presented by Appellants demonstrating expression of the fatty acid desaturases and working examples demonstrating expression of at least 11 different transgenes and generation of at least 267 different transgenic lines more than adequately does so. Faced with the failure of the Examiner to provide ***any*** evidence to doubt enablement of the claims as set forth in part (2) above, the rejection cannot stand.

3. Genentech is Inapposite

The Answer asserts that Appellants' demonstration of the inapplicability of the *Genentech* ruling to the current facts was unpersuasive and that the case is "eminently applicable to the instant fact pattern." Answer at p. 16, 3rd full ¶. For example, it was asserted that in *Genentech* claims directed to a method of cleaving undisclosed conjugate proteins were not enabled by a specification that merely suggested the desirability of the cleavage, given the disclosure of a DNA molecule encoding a particular growth hormone, together with knowledge in the art of cleavable fusion expression techniques. It was thus concluded that *Genentech* found that prior art knowledge of trypsin as a potential cleavage agent was insufficient to enable the claimed invention and that this is applicable to the current situation because "Appellant has provided even less information than the Genentech patent which the Court ultimately found invalid." Answer at p. 17, 1st full ¶.

In *Genentech* the relevant items asserted to be missing from the specification were reaction conditions for making cleavable fusion expressions and steps for making hGH. 42 USPQ 2d 1001, 1004 (Fed. Cir. 1997). The Court rejected notions that these elements were in the prior art because, as of the filing date, there was not a single example of a human protein produced via cleavable fusion protein expression. *Id.* at 1006. This was despite the presence of human proteins in the art and a "great many researchers" attempting to produce recombinant proteins. *Id.* In addition, the specification did not describe "any detail whatsoever" about how to obtain the claimed hGH cleavable fusion expression. *Id.* at 1004. In contrast, the element that is alleged to be lacking here, fatty acid desaturase genes, was in fact well known as of the effective filing date as fully demonstrated in Appellants' Brief.

Exhibits A-G alone demonstrate at least nine examples of known fatty acid desaturases. In addition, the working examples provide detailed teaching demonstrating the successful

transgenic expression of numerous foreign genes in maize. Table 8 of the specification, for example, states that fertile transgenic plants were obtained from 267 different transgenic lines. Table 9 shows that R0 transgenic plants were obtained expressing at least the following genes: a *uidA* reporter gene, a *bar* selectable marker gene conferring herbicide tolerance, a *hyg* gene conferring resistance to hygromycin, an *aroA* gene conferring tolerance to the herbicide glyphosate, a *Bacillus thuringiensis* endotoxin gene, and a Z10 altered seed storage protein. Maize callus cells were also obtained transformed with a C1 anthocyanin pigmentation gene, a *lux* luciferase reporter gene, potato and tomato *pinII* proteinase inhibitor genes conferring insect resistance, an *mtlD* protein conferring enhanced stress resistance and a *deh* gene conferring resistance to dalapon herbicide. Given these examples, it would have been routine for one of skill in the art to express a fatty acid desaturase using the same methods and simply replacing any of the many coding sequences with the fatty acid desaturase sequence. These examples therefore fully demonstrate the enablement of the claims and lack of applicability of the *Genentech* holding.

4. The Ursin Declaration Demonstrates Enablement of the Claims

The Answer asserts that the Ursin Declaration is not persuasive because it used a "non-exemplified" method of maize transformation and simultaneous expression of two desaturases "one of which was mutated." Appellants initially note in response that the first assertion is completely irrelevant. The Examiner ***does not contest*** that Appellants' specification is enabling for maize transformation and the mode of introduction of the transgene is irrelevant to the issue of whether the transgene would express or cause phenotypic change. The end result is the introduction of the transgene into the genome of a maize plant regardless of the method used. The Examiner's allegations that the mode of transformation has any relevance to the ability to

express the transgene and the applicability of the Ursin Declaration are therefore unsupported and incorrect.

Regarding the use of two transgenes or that one of them was "mutated," this also in no way negates the showing made by Dr. Ursin. If anything, it demonstrates the ability to express two transgenes, at least one of which was not "mutated." As stated by Dr. Ursin, the results demonstrated that expression of a fatty acid desaturase gene in maize alters the fatty acid profile in a manner that renders the transgenic plants identifiable over a corresponding non-transgenic plants. Dr. Ursin also explains that the results confirm that the alteration of fatty acid profiles occurs in a ***predictable manner*** consistent with the enzymatic activity of the fatty acid desaturase that is introduced. Coupled with the numerous working examples in the specification demonstrating the ability to routinely and predictably express a diverse collection of transgenes in maize, this more than adequately demonstrates enablement.

5. Appellants' Confirmation of "Past Failures of Others" Does Not Negate Enablement

The Answer concludes by asserting that "Appellants confirmed the veracity of the Examiner's arguments regarding lack of enablement" by referring to the past failures of others in the traversal of an obviousness rejection on page 9 of the Response to Office Action of October 18, 2004. The relevant section referred to the lack of engineering of grain composition traits in maize prior to applicants invention and the difficulty of others in transforming maize specifically, *e.g.*, the failure of the prior art to transform and express transgenes in maize. This section also quoted contradictory statements made by the Examiner. However, the past failures of others referred to was with respect to the ability to transform and express transgenes in maize, which problem the specification fully solves. In particular, the specification demonstrates the expression in maize cells of at least ***11 different transgenes and recovery of at least 267***

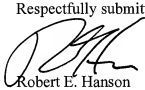
different transgenic lines. Specification Tables 8 and 9. In the case of 6 different transgenes, transgenic plants expressing the relevant transgenes were regenerated. The transgenes that were expressed were diverse in mode of action and phenotype conferred, and included genes conferring tolerance to multiple herbicides and antibiotics (*bar*, *hyg*, *aroA*, *deh*), insect resistance genes (*Bt*, tomato and potato *PinII*), a seed storage protein gene (*Z10*), screenable color or enzymatic reporter genes (*C1*, *uidA*, *lux*), and a drought tolerance gene (*mtlD*). These examples more than adequately demonstrate that the specification enables the reliable and predictable expression of heterologous genes in maize without undue experimentation.

In sum, the claims are fully enabled and the Examiner has presented no reasonable basis for concluding otherwise. Reversal of the rejection is thus respectfully requested.

CONCLUSION

It is respectfully submitted, in light of the above, that none of the claims are properly rejected. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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Date: November 13, 2006

VIII. CLAIMS APPENDIX

2. Cells obtained from the plant of claim 67 or 68, wherein said cells comprise the DNA composition.

3. Progeny of the plant of claim 67 or 68, wherein said progeny comprise the DNA composition.

4. Seeds obtained from the plant of claim 3, wherein said seeds comprise the DNA composition.

67. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait comprising a fatty acid desaturase gene so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

IX. EVIDENCE APPENDIX

(Exhibits A – H were previously submitted with Appellants Appeal Brief)

Exhibit A: McDonough *et al.* (*J Biol Chem.* 1992 Mar 25;267(9):5931-6); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit B: Fox *et al.* (*Proc Natl Acad Sci U S A.* 1993 Mar 15;90(6):2486-90); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit C: Reddy *et al.* (*Plant Mol Biol.* 1993 May;22(2):293-300); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit D: Arondel *et al.* (*Science.* 1992 Nov 20;258(5086):1353-5); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit E: PCT Application Publ. No. WO 91/13972; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit F: European Patent Application Publ. No. EP 0616644; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit G: European Patent Application Publ. No. 0537178; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit H: Declaration of Dr. Virginia Ursin; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action.

X. RELATED PROCEEDINGS APPENDIX

Board Decision in Ser. No. 09/081,416

Board Decision in Ser. No. 09/732,439

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PAUL C. ANDERSON, PAUL S. CHOMET, MATTHEW C. GRIFFOR, and ALAN L. KRIZ

Appeal No. 2006-0102
Application No. 09/732,439

ON BRIEF

Before SCHEINER, ADAMS, and GRIMES Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 59-63, 72 and 73. The only remaining claims, claims 64-71 and 74-96 were withdrawn from consideration as drawn to a non-elected invention.

Claims 59 and 61 are illustrative of the subject matter on appeal and are reproduced below:

59. A transformed monocot plant, which plant is substantially tolerant or resistant to a reduction in water availability, the cells of which comprise a recombinant DNA segment comprising a preselected DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, wherein the enzyme is expressed in an amount effective to confer tolerance or resistance to the transformed plant to a reduction in water availability.

61. A fertile transgenic Zea mays plant comprising a recombinant DNA segment comprising a promoter operably linked to a first DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, wherein the first DNA segment is expressed so that the level of the enzyme is increased in transgenic Zea mays plant, and wherein the recombinant DNA segment is heritable.

The references relied upon by the examiner are:

Verma et al. (Verma I)	5,344,923	Sep. 6, 1994
Verma et al. (Verma II)	5,639,950	Jun. 17,1997
Adams et al. (Adams '98)	5,780,709	Jul. 14, 1998
Adams et al. (Adams '01)	6,281,411	Aug. 28, 2001

Barnett et al. (Barnett), "Amino acid and protein metabolism in Bermuda grass during water stress," Plant Physiol., Vol. 41, pages 1222-1230 (1966)

Jones et al. (Jones), Physiology and Biochemistry of Drought Resistance in Plants, Ch. 9, Betaines, pp. 171-204 (Academic Press, Australia) (1981)

Rayapati et al. (Rayapati), "Pyrroline-5-Carboxylate Reductase Is in Pea (Pisum sativum L.) Leaf Chloroplasts," Plant Physiol., Vol. 91, pp. 581-586 (1989)

McCue et al. (McCue), "Drought and salt tolerance: towards understanding and application," TIBTECH, Vol. 8, pages 358-362 (1990).

Brandriss et al. (Brandriss), "Proline biosynthesis in Saccharomyces cerevisiae: analysis of the PRO3 gene, which encodes Δ^1-pyrroline-5-Carboxylate reductase," J. Bact., Vol. 174, No. 15, page 5 176 (1992)

Dougherty et al. (Dougherty), "Cloning human pyrroline-5-carboxylate reductase cDNA by complementation in Saccharomyces cerevisiae," J. Biol. Chem., Vol. 267, No. 2, pages 871-875 (1992)

Hu et al. (Hu), "A bifunctional enzyme (Δ^1-pyrroline-5-carboxylate synthetase) catalyzes the first two steps in proline biosynthesis in plants," Proc. Natl. Acad. Sci., USA, Vol. 89, pages 9354-9358 (1992)

Van Rensburg et al. (Van Rensburg), "Proline accumulation as drought tolerance selection criterion: its relationship to membrane integrity and chloroplast ultrastructure in Nicotiana tabacum L.," J. Plant Physiol., Vol. 141, page 188-194 (1993)

GROUNDS OF REJECTION

Claims 59-63, 72 and 73 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification that fails to adequately describe the claimed invention.

Claims 59-63, 72 and 73 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure that fails to enable the claimed invention.

Claims 61-63 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the term "increased."

Claims 59-61, 63, 72 and 73 stand rejected under 35 U.S.C. § 102(e), as being anticipated by Verma II.

Claims 59-63, 72 and 73 stand rejected under 35 U.S.C. § 103, as being unpatentable over the combination of Verma II and Rayapati.

We affirm the rejection under the written description provision of 35 U.S.C. § 112, first paragraph. We reverse the rejections under 35 U.S.C. § 112, second paragraph, § 102(e), and § 103. Having disposed of all claims under the written description provision of 35 U.S.C. § 112, first paragraph, we do not reach the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

DISCUSSION

Definiteness:

Claims 61-63 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the term "increased." According to the examiner

(Answer, page 11), the term "increased is a relative term lacking a comparative basis."

In response, appellants assert (Brief, page 8), "[a] plain reading of the claim indicates that the enzyme is increased relative to a Zea mays plant that lacks the recombinant DNA segment. No other logical reading can be made of the claim given the text." "The Examiner does not dispute that a plain reading of the claim could indicate that the enzyme is increased relative to a Zea mays plant that lacks the recombinant DNA segment." Answer, page 24. Nevertheless, the examiner finds (id.), "a plain reading of the claim could also indicate that the enzyme is increased relative to the level of the endogenous enzyme in the transgenic Zea mays plant. . . ." It would appear to us that this interpretation of term "increased" is the same as interpreting the claim to read "an increase relative to a Zea mays plant that lacks the recombinant DNA segment." Accordingly, we are not persuaded by the examiner's argument.

Alternatively, the examiner asserts that the term "increased" could be interpreted to be "relative to the level of the enzyme produced under non-stress conditions. . . ." We must confess that we are somewhat confused as to the basis for the examiner's argument. According to appellants' specification (page 5):

> [t]he enzyme encoded by the DNA sequence is expressed in the transgenic Zea mays plant or cell so that the level of the osmoprotectant in the cells of the transgenic Zea mays plant is substantially increased above the level in the cells of a Zea mays plant which only differ from the cells of the transgenic Zea mays plant in that the DNA segment is absent.

Therefore when the claims are read in light of appellants' specification it would appear that the claimed transgenic Zea mays plant, which comprises a DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, grown under non-stress conditions would express the enzyme at an increased level relative to a Zea mays plant grown under non-stress conditions and does not comprise a DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline. As we understand appellants' claims when read in light of the appellants' specification, the same would be true if both plants were grown under stress conditions – the transgenic Zea mays plant would express the enzyme at an increased level relative to a Zea mays plant that does not comprise the DNA segment encoding the enzyme.

As set forth in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991):

> The statute requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits.").

Furthermore, claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

For the foregoing reasons we find that appellants' claims, when read in light of appellants' specification, are definite. Accordingly, we reverse the rejection of claims 61-63 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 59-63, 72 and 73 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification fails to adequately describe the claimed invention. Appellants do not separately group or provide separate arguments for the claims under rejection. Accordingly the claims will stand or fall together. Since all claims stand or fall together, we limit our discussion to representative independent claim 59. Claims 60-63, 72 and 73 will stand or fall together with claim 59. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to appellants' specification (page 4),

> an "osmoprotectant" is an osmotically active molecule which, when that molecule is present in an effective amount in a cell or plant confers water stress tolerance or resistance, or salt stress tolerance or resistance, to that cell or plant. Osmoprotectants include sugars such as monosaccharides, disaccharides, oligosaccharides, polysaccharides, sugar alcohols, and sugar derivatives, as well as proline and glycine-betaine.

According to the examiner (Answer, page 7), claim 59 is "drawn to a transformed monocot plant . . . comprising a recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline." The examiner finds, however, that claim 59 does "not recite the specific identity of any particular recombinant [proline] DNA" with which the plant has been

transformed. Id. In this regard, the examiner finds (Answer, page 15), the phrase "recombinant DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline" encompasses a genus of DNAs "of any sequence", "obtained from any source", "encoding any enzyme of any type", "which catalyzes the synthesis of the osmoprotectant proline." According to the examiner (Answer, bridging sentence, pages 15-16), appellants' specification does not disclose or refer to any DNA segment or enzyme within this genus. Specifically, the examiner finds (Answer, page 7),

> the specification does not describe any plant comprising any recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline. The specification also does not describe any recombinant DNA encoding any enzyme which catalyzes the synthesis of the osmoprotectant proline. Given that proline is an amino acid found in virtually all organisms, a variety of structurally and functionally distinct proline biosynthetic enzymes exist that are encoded by genes from divergent plant, animal and microbial species.

Therefore, the examiner concludes (Answer, page 8),

> Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized [a]ppellants to have been in possession of the claimed invention at the time of filing.

In response, appellants assert (Brief, page 4) "that genes encoding enzymes that elevate the level of proline were known in the art at the time of filing." In this regard, appellants direct attention (Brief, pages 4-5) to the following references:

1. Verma I, for a disclosure of mothbean Δ^1-pyrroline-5-carboxylate synthetase (P5CS).

2. Hu, for a disclosure of a "soybean homologue" of Δ^1-pyrroline-5-carboxylate synthetase (P5CS); however, Hu discloses only the mothbean PSC (see the abstact).

3. Verbruggen[1].

4. Dougherty, for a disclosure of human pyrroline-5-carboxylate reductase (P5CR).

5. Brandriss, for a disclosure of yeast Δ^1-pyrroline-5-carboxylate synthetase (P5CS).

6. Williamson[2].

Based on the foregoing, appellants assert (Brief, page 5), since "these sequences were known to those of skill in the art at the time of filing, [a]ppellants cannot be said to lack written description for these sequences."

In response, the examiner asserts (Answer, page 15), "[t]hat some genes encoding enzymes involved in proline biosynthesis were known in the art at the time of filing does not demonstrate that [a]ppellants were in full possession of the claimed genus. . . ." More specifically, the examiner finds (Answer, bridging paragraph, pages 16-17) that knowledge in the art of two enzymes involved in proline biosynthesis (1) Δ^1-pyrroline-5-carboxylate synthetase from mothbean (Verma and Hu), and (2) human (Dougherty) and yeast (Brandriss) pyrroline-5-carboxylate reductase are not sufficient to represent the entire

[1] Verbruggen et al. (Verbruggen), "Osmoregulation of a pyrroline-5-carboxylate reductase gene in Arabidopsis thaliana," Plant Physiol., Vol. 103, No. 3, pages 771-781 (1993). According to the examiner (Answer, page 17), Verbruggen published November 1993, after appellants' August 25, 1993 effective filing date, and therefore cannot be relied upon in support of appellants' claimed invention. Accordingly, we have not considered appellants' arguments with regard to this reference.

[2] Williamson et al. (Williamson), "Molecular Cloning and Evidence for Osmoregulation of the Δ1-Pyrroline-5-Carboxylate Reductase (proC) Gene in Pea (Pisum sativum L.)," Plant Physiol., Vol. 100, pp. 1464-1470 (1992). According to the examiner (Answer, page 17), this reference was not properly made of record in the application and therefore was not considered. Accordingly, we have not considered appellants' arguments with regard to this reference.

genus of recombinant DNA segments that encode enzymes that catalyze the synthesis of proline and would be capable of being "expressed in a plant in an amount effective to confer tolerance or resistance to a reduction in water availability" as encompassed by claim 59. In this regard, we find that the evidence of record establishes that as of appellants' filing date three distinct pathways were known to exist for the production of proline. See e.g., Verma I, figure 4. The references relied upon by appellants teach the enzymes involved in the plant pathway:

While the P5CR enzyme taught by the evidence of record is involved in the last step (P5C → Proline) of the proline biosynthetic pathway in bacteria - bacteria utilize two separate enzymes (γGK and GSD) to convert glutamate to GSA as opposed to the single P5CS bifunctional enzyme utilized by plants. Id., and column 3, lines 41-58. Appellants fail to direct our attention to any evidence of record, and we find none, that teaches the enzymes involved in the third pathway for proline biosynthesis, which involves the intermediate ornithine. Verma I, figure 4.

Therefore, as we understand the evidence of record, while there are three separate pathways for the biosynthesis of proline, which appear to utilize a number of different enzymes, appellants would assert that the knowledge in the art of P5CS and P5CR is representative of the entire genus of enzymes involved in proline biosynthesis. We disagree.

When faced with circumstances similar to those at issue here, our appellate reviewing court has held claims to lack adequate description. For example, in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), our appellate reviewing court held that claims generically reciting cDNA encoding vertebrate or mammalian insulin were not adequately described by the disclosure of cDNA encoding rat insulin. Id. at 1568, 43 USPQ2d at 1406. The court held that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. The court described two ways of properly describing a claimed genus:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. The court has since clarified that the description of representative species does not necessarily have to include their complete structure (nucleotide sequence). See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

The Eli Lilly court held that a fully described genus is one for which a person skilled in the art can "visualize or recognize the identity of the members of the genus." On this record, as the examiner points out (Answer, page 16),

"[n]either [a]ppellants' specification nor the prior art identify any conserved sequences within the broad genus of any proline biosynthetic enzyme[s] or any gene encoding it, wherein such conserved sequences are correlated with the involvement in proline biosynthesis." Stated differently, the evidence of record fails to recite the structural features common to the members of the genus, which features constitute a substantial portion of the genus. In addition, as discussed above, appellants' specification fails to provide a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the claimed genus. Since the specification does not describe the claimed DNAs adequately for those skilled in the art to distinguish the claimed DNAs from other DNAs, the specification does not adequately describe the claimed DNAs under the standard of Eli Lilly.

Adding to the complexity of the claimed invention, the examiner finds (id.) that according to claim 59, the recombinant DNA must encode an enzyme that has "the capacity to be expressed in a plant in an amount effective to confer tolerance or resistance to a reduction in water availability." According to the examiner (id.), appellants' "specification does not indicate which genes encoding which enzymes would have this capacity."

"The 'written description' requirement serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted). Another "purpose of the 'written

description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date . . . [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116).

On this record, we agree with the examiner that appellants' disclosure does not convey with reasonable clarity that, as of the filing date, appellants were in possession of a genus of DNA segments that encode an enzyme which catalyzes the synthesis of the osmoprotectant proline, and would be capable of being "expressed in a plant in an amount effective to confer tolerance or resistance to a reduction in water availability" as encompassed by claim 59. At best, appellants have established that two such genes, Δ^1-pyrroline-5-carboxylate synthetase and pyrroline-5-carboxylate reductase, were known in the art at the time their invention was made. For the foregoing reasons, we agree with the examiner that these two genes are not sufficient to describe the entire genus encompassed by appellants' claim.

On reflection, we find that the weight of the evidence falls in favor of the examiner. Accordingly, we affirm the rejection of claim 59 under the written description provision of 35 U.S.C. § 112, first paragraph. As discussed supra claims 60-63, 72 and 73 fall together with claim 59.

Enablement:

Claims 59-63, 72 and 73 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure that fails to enable the claimed invention.

Having disposed of all claims under the written description provision of 35 U.S.C. § 112, first paragraph, we do not reach the merits of the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

Anticipation:

The instant application is a divisional of United States Application No. 08/599,714, filed January 19, 1996, now United States Patent No. 6,281,411 ('411). The '411 patent is a continuation-in-part of United States Application No. 08/113,561 ('561), filed August 25, 1993. According to appellants (Brief, page 9), the instant application claims priority to the '561 application filed August 25, 1993. The examiner does not dispute that the instant application receives benefit of the filing date of the '561 application. Therefore, the effective filing date of the instant application is August 25, 1993.

Claims 59-61, 63, 72 and 73 stand rejected under 35 U.S.C. § 102(e), as being anticipated by Verma II. Verma II was filed on June 29, 1994, after the effective filing date of the instant application. The examiner recognizes, however, that Verma II is a continuation-in-part of Verma I, which has a filing date of September 29, 1992. Accordingly, the examiner relies on the September 29, 1992 effective filing date of Verma II. We note, however, that in doing so the examiner can only rely on the subject matter disclosed in Verma II that is also disclosed in Verma I. Any subject matter in Verma II that is not present in Verma I does not receive the benefit of the September 29, 1992 filing date. In this regard, we note that the examiner concedes that Verma I does not disclose the subject matter of the invention before us on appeal - a transformed monocot plant. Answer, page 26.

As we understand the examiner's findings, Verma I teach mothbean plants (dicots) transformed with a recombinant Δ^1-pyrroline-5-carboxyl synthetase and suggest that "it would be desirable to use genetic engineering of the proline production pathway in plants to counter osmotic stress. . . ." Answer, page 27. According to the examiner (Answer, page 30), since monocot transformation was known in the art as of the filing date of Verma I, neither Verma I nor Verma II need to "disclose a method for transforming monocots and teach transformation vectors that could be used to achieve gene expression in monocots. . . ."

The examiner then leaps to the Verma II disclosure finding (Answer, page 12) that Verma II "teach corn, wheat, barley and rye monocot plants comprising a

recombinant DNA encoding Δ^1-pyrroline-5-carboxylate synthetase which catalyzes the synthesis of the osmoprotectant proline (column 17, claim 5 and column 18, claim 14)." The examiner reasons (id.), since Verma II discloses that the monocot plants are drought resistant, the Δ^1-pyrroline-5-carboxylate synthetase must be "expressed in an amount effective to confer tolerance or resistance to a reduction in water availability. . . ." Verma II is not entitled to the benefit of the September 29, 1992 filing date of Verma I for subject matter that is disclosed in Verma II but not in Verma I. Specifically, since Verma I does not disclose monocots transformed with Δ^1-pyrroline-5-carboxylate synthetase, Verma II does not receive the benefit of Verma I's filing date for this subject matter. Instead, the new subject matter disclosing transformed monocots present in Verma II receives benefit of the June 29, 1994 filing date of Verma II, which is after the August 25, 1993 effective filing date of the instant invention.

Therefore despite the examiner's assertion (Answer, page 26) that the methodology used by Verma II to transform monocots is the same as that used by Verma I to transform dicots, there is no evidence on this record that Verma I or Verma II disclosed a monocot transformed with Δ^1-pyrroline-5-carboxylate synthetase as of the August 25, 1993 effective filing date of the present application. "Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in

the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Since there is no evidence on this record that every limitation of appellants' claimed invention was disclosed in either Verma I or Verma II prior to appellants' effective filing date the anticipation rejection of record cannot be maintained. Accordingly, we reverse the rejection of claims 59-61, 63, 72 and 73 under 35 U.S.C. § 102(e), as being anticipated by Verma II.

Obviousness:

Claims 59-63, 72 and 73 stand rejected under 35 U.S.C. 103, as being unpatentable over the combination of Verma II and Rayapati.

The examiner relies on Verma II as set forth above. Answer, page 13. As discussed above, Verma II does not disclose a transformed monocot prior to appellants' effective filing date. Further, the examiner finds (Answer, page 13), Verma II does "not teach a DNA segment encoding an amino terminal chloroplast transit peptide." The examiner relies on Rayapati to make up for the deficiencies in Verma. Id.

According to the examiner (Id.), Rayapati "teach that the proline biosynthetic enzyme Δ^1-pyrroline-5-carboxylate reductase (Δ^1-pyrroline-5-carboxylate synthetase) is localized in chloroplasts (page 582 column 2 last paragraph through page 583 column 2 second full paragraph)."[3] For clarity, we note that the chloroplasts were isolated from "Peas (Pisum sativum L. var

Argenteum)" – a dicot. Rayapati, page 581, column 2, "Plant Material." We do not find, and the examiner has not identified a disclosure in Rayapati, of a transformed monocot plant. Therefore, while the examiner may assert (Answer, page 14), "[m]ethods for transforming monocots such as maize via electroporation or biolistics were well-known in the art at the time of [a]ppellants' invention, namely August 1993," there is no evidence on this record to support this assertion.

Nevertheless, the examiner concludes (Answer, page 14),

> it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to transform a plant with a recombinant DNA encoding both a proline biosynthetic enzyme and a chloroplast transit peptide, give [sic] the express purpose of making a transgenic drought-resistant plant. . . .

We disagree.

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. . . . Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."
>
> . . .
>
> Most if not all inventions arise from a combination of old elements. . . .Thus, every element of a claimed invention may often be found in the prior art. . . . However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. . . . Rather, to establish obviousness

[3] In addition, the examiner finds (Id.), "[a]ppellants teach that DNA segments encoding amino terminal chloroplast transit peptides were well-known and used in the plant transformation art at the time of Applicant's invention (page 39 lines 7-9)."

> based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [Citations omitted].

In other words, "there still must be evidence that 'a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000).

As discussed above, there is no evidence on this record that would suggest a transformed monocot plant within the scope of appellants' claimed invention. At best, the evidence would suggest producing a transformed dicot plant. While the examiner asserts that methodology was available in the art as of appellants' effective filing date to produce a transformed moncot, the examiner fails to favor this record with any evidence to support this assertion, as well as to suggest that a person of ordinary skill in the art would have been motivated to do so at the time of appellants' effective filing date.

For the foregoing reasons we are compelled to reverse the rejection of claims 59-63, 72 and 73 under 35 U.S.C. § 103, as being unpatentable over the combination of Verma II and Rayapati.

SUMMARY

We affirm the rejection of claims 59-63, 72 and 73 under the written description provision of 35 U.S.C. § 112, first paragraph.

We do not reach the merits of the rejection of claims 59-63, 72 and 73 under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 61-63 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 59-61, 63, 72 and 73 under 35 U.S.C. § 102(e).

We reverse the rejection of claims 59-63, 72 and 73 under 35 U.S.C. § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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Attorney DLP/REH/RJL
Docket No. AD-DEKM:055US03
Action Req'd Date Due

Request for Reconsideration 10/28/06

Request Oral Hearing 10/28/06

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS R. ADAMS, PAUL C. ANDERSON, WILLIAM J. GORDON-KAMM, ALBERT P. KAUSCH, and PETER M. ORR

Appeal No. 2006-1382
Application No. 09/081,416

HEARD: July 13, 2006

Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 98-100 are pending. Claims 1-97 and 101-109 have been cancelled.

Claim 98 is representative and read as follows:

98. A transformed monocot plant, the genome of which has been augmented by a DNA composition comprising a preselected DNA segment comprising a DNA sequence which encodes the Late Embryonic Protein HVA-1, wherein the preselected DNA segment is transmitted through a normal sexual cycle of the monocot plant to its progeny, and wherein said plant expresses said Late Embryonic Protein to impart drought resistance to the plant.

100. The plant of claim 98, wherein the plant is *Zea Mays*.

The prior art references cited by the examiner are:

Tomes et al. (Tomes)	5,990,387	Nov. 23, 1999
Goldman et al. (Goldman)	6,020,539	Feb. 1, 2000
Rogers	5,677,474	Oct. 14, 1997

Fitzpatrick et al., Genetic Engineering News, Vol. 13, No. 5, p. 1 (1993)

Grounds of Rejection

Claims 98-100 stand rejected under 35 U.S.C. § 103(a) over Fitzpatrick in view of one of Tomes, Rogers and Goldman.

We affirm the rejection under 35 U.S.C. § 103(a) over Fitzpatrick and Tomes. We do not reach the rejections over Fitzpatrick and Rogers, and Fitzpatrick and Goldman.

DISCUSSION

Obviousness

Claims 98-100 stand rejected under 35 U.S.C. § 103(a) over Fitzpatrick in view of one of Tomes, Rogers and Goldman.

Claims 98-100 are pending. Appellants provide separate argument with respect to claims 98 and 100. We select these claims as representative.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

According to the examiner (Answer, page 3), "Fitzpatrick teaches a transformed tobacco (dicot) plant expressing a barley LEA protein, wherein said plant is drought tolerant (p. 6). Fitzpatrick further teaches monocots such as barley, wheat and rice could also be transformed with the LEA protein to withstand drought stress and requiring less watering (p. 22). Fitzpatrick disclosed that drought is by far the leading stress in agriculture worldwide (p. 22). The tobacco transformation was Agrobacterium tumefaciens mediated, which would indicate stable genomic transformation; and thus the LEA gene would be transmitted through normal sexual cycle of the plant to its progeny (p. 22)."

"Even though Fitzpatrick suggests transformation of various monocots, Fitzpatrick does not teach actual transformation of a monocot such as Zea mays (corn). ...." Id.

> Tomes teaches the stable transformation of Zea mays (corn) plants with a DNA sequence of interest (column 1, lines 36-46). Tomes specifically demonstrated transformation of corn (column 6, lines 52-67), and disclosed that the techniques taught therein, were also applicable to other monocots including oat, barley and wheat (column 4, lines 31-38). Tomes also taught that the monocot plant was regenerated into a whole, fertile plant (column 7, lines 76-77, and lines 66-67).

Id.

The examiner concludes (Answer, pages 4-5)

> it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to transform a monocot such as oat, wheat, barley or corn with the LEA gene of Fitzpatrick using the monocot transformation method as taught by ... Tomes, ...for the purpose of generating a drought tolerant monocot plant. Heterologous protein expression in monocots was well known in the art, as evidenced by ... Tomes ... Moreover, the LEA gene was known, and its drought tolerance property was known, as taught by Fitzpatrick. The motivation to transform a monocot with the LEA gene to generate a drought tolerant monocot was also taught by Fitzpatrick. There is no evidence that expression of the LEA protein of Fitzpatrick in a monocot would have a different or detrimental effect on a monocot. After all, the LEA protein of Fitzpatrick was isolated from barley, a monocot. There is no evidence that transformation of corn would have surprising or unexpected results from transformation of oat, wheat and barley. Thus one skilled in the art would have been motivated to express the LEA protein of Fitzpatrick in any of Applicant's claimed monocot using the monocot transformation method of ... Tomes ... for the purpose of imparting drought tolerance to a monocot with a reasonable expectation of success.

We find the examiner has provided sufficient evidence to support a prima facie case of obviousness. Fitzpatrick describes the incorporation of the LEA gene from barley (a monocot) into a dicot plant, tobacco, for the purpose of imparting drought tolerance. Fitzpatrick provides a suggestion and motivation to impart the same drought resistance into monocot plants. Tomes provides a method for the stable transformation of plant cells, including monocot plant cells, with preferred plants indicated to be maize, rye, barley, wheat, sorghum, oats, millet, rice, sunflower, alfalfa, rape seed and soybean. Col. 4, lines 31-34. Tomes describes the transformation of monocot germ line cells, such as callus cells, using a microparticle bombardment method (col. 3, lines 20-24 and col. 4, lines 39-530), a method similar to that used to obtain the claimed transformed monocot. The use of a cauliflower mosaic virus promoter, similar to that used to obtain the claimed transformed monocot, is also suggested in method of Tomes. Col. 2, lines 43-45. Moreover, with respect to claim 100, Tomes claims a method of producing a fertile, stably transformed Zea Mays plant by introducing a foreign DNA into an embryonic callus of Zea Mays by one or more particle bombardments.

Given the teachings of Tomes with respect to the ability to stably transform the germ line cells of monocots such as corn (claim 100) and barley (claims 98 and 99) with foreign DNA using microparticle bombardment, and the express suggestion in Fitzpatrick that it is possible to confer drought resistance to dicots such as tobacco using LEA protein from barley and desirable to also transform monocots, such as corn

and barley in a similar manner, one of ordinary skill in the art would have been motivated to, and would have had a reasonable expectation of success of conferring drought resistance in barley using the barley LEA protein and the monocot transformation method of Tomes. Based on the evidence of record one of ordinary skill in the art would also have had an expectation of success of transforming corn (claim 100) by the method of Tomes with barley LEA protein HVA-1. The evidence before us reasonably appears to support a prima facie case of obviousness.

In response, appellants argue that "Tomes [ ] is entirely prophetic with regard to transgenic corn plants. The working examples discuss transgenic maize cells and transgenic tobacco plants, but do not provide transgenic maize plants, let alone maize plants expressing heterologous DNA." Supplemental Brief, page 9. Appellants further argue that, "given the complexity of successfully introducing and expressing a given coding sequence, and lack of demonstration by the Examiner of a single actual fertile transgenic corn plant in the prior art, an expectation of success would have been absent..." Id.

We are not persuaded by appellants' arguments. Appellants have merely provided attorney argument regarding the complexity of successfully introducing and expressing a given coding sequence in a monocot. Appellants are reminded that arguments of counsel cannot take the place of evidence. In re DeBlauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984), In re Payne, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979). Moreover, appellants fail to present any evidence to

support their position that Tomes lacks an enabling disclosure, or evidence that one of ordinary skill in the art would have lacked an expectation of success, such as evidence of difficulties in using the barley LEA protein (HVA-1) to transform other types of plants, or other factors that one of ordinary skill in the art would have considered to impact the expectation of success with respect to obtaining a transformed corn plant (claim 100). The examiner argues "there is no patent law, rule or regulation that requires that the cited reference in a rejection must teach an actual transgenic corn plant, so long as its disclosure is enabling." Answer, page 10.

Appellants direct the examiner's attention to Adang v. Fischoff, 286 F.3d 1346, 62 USPQ 1504 (Fed. Cir. 2002) to support their argument regarding a lack of reasonable expectation of success. Appellants acknowledge (Brief, page 9) that in Adang, the patent owner cited evidence that bioassays could vary even among different strains of tobacco. We find the citation of Adang to be inapt here. First, in the present case appellants have not put forth any evidence to support their position of lack of reasonable expectation of success, such as that proffered in Adang, for example, evidence of consistent difficulties in using the LEA protein to transform other types of plants. Nor has evidence been presented to suggest that one of ordinary skill in the art would not have expected a monocot LEA protein from barley to successfully confer drought resistance in a monocot barley plant, or a corn plant (claim 100).

Appellants summarily argue that "the expression of a given transgene in tobacco would ... not have lead to a reasonable expectation of success in expressing the same

gene in monocots..." Brief, page 8. However, the combination suggested by the examiner involves the transformation of a monocot, barley plant, with a monocot, barley, LEA protein. While, one of ordinary skill in the art may have recognized that it would have been more difficult to transform a dicot, tobacco, with an unrelated monocot gene from barley as successfully performed in Fitzpatrick, they would have also recognized that there would have been a reasonable expectation of success of the ability to stably transform a monocot, barley, with a related monocot, barley LEA protein, as suggested by the cited references.

Nor do we find appellants' argument regarding the examiner's statements with respect to a withdrawn enablement rejection to be convincing here. Brief, page 10. The examiner admitted an error and withdrew the lack of enablement rejection after appellants' Declaration evidenced that the state of the art was such that one of ordinary skill in the art at the time of appellants' invention would have found appellants' disclosure enabling.

CONCLUSION

We affirm the rejection under 35 U.S.C. § 103(a) over Fitzpatrick and Tomes. We do not reach the rejection over Fitzpatrick and Rogers and Fitzpatrick and Goldman.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 2006-1382
Application No. 09/081,416

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